UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/573,909	01/08/2007	Joel Barry Baseman	9237-10	9089

20792 7590 01/30/2009

MYERS BIGEL SIBLEY & SAJOVEC
PO BOX 37428
RALEIGH, NC 27627

EXAMINER	
DEVI, SARVAMANGALA J N	
ART UNIT	PAPER NUMBER
1645	
MAIL DATE	DELIVERY MODE
01/30/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/573,909	BASEMAN ET AL.	
	Examiner	Art Unit	
	S. Devi, Ph.D.	1645	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *102908*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-7 and 9-32* is/are pending in the application.

4a) Of the above claim(s) *1, 2, 6, 7, 9, 10 and 14-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,5,12 and 13* is/are rejected.

7)☒ Claim(s) *3 and 11* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *032906* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *112006 & 092606*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Preliminary Amendment

1) Acknowledgement is made of Applicants' preliminary amendment filed 03/29/06.

Election

2) Acknowledgement is made of Applicants' election filed 10/29/08 in response to the lack of unity mailed 09/29/08. Applicants have elected, with traverse, invention II, claims 3-5 and 11-13.

Applicants provisionally elect invention II, claims 3-5 and 11-13, with traverse. Applicants traverse the restriction on the basis that inventions I-IX all relate to a single general inventive concept under PCT Rule 13.1 and should be examined together. Applicants contend that the amino acid sequence shown on pages 2-4 of the Sequence Listing of the Chiron publication (WO 02/079242) is a 571 amino acid sequence that is not identical to any of the amino acid sequences of SEQ ID NO:2, 3, 4, 5, or 6 of the present invention (see, e.g., amino acid 371, which is isoleucine in SEQ ID NO:4 of the Chiron publication and which is serine in each of SEQ ID NOs: 2, 3, 4, 5 and 6 of the present invention). Applicants submit that the Chiron publication does not show or describe any fragments of SEQ ID NO: 4 on pages 2-4 of the Sequence Listing. Applicants submit that since a polypeptide comprising an amino acid sequence of SEQ ID NO: 2, 3, 4, 5, or 6 is a unifying feature of all of the claims of all of Groups I-IX, which are all directed to these polypeptides, nucleic acids encoding these polypeptides and antibodies specifically reactive with these polypeptides, as well as methods and kits employing these polypeptides, nucleic acids and antibodies have unity and should all be examined together in the present application.

Applicants' arguments have been carefully considered, but are not persuasive. Contrary to Applicants' assertion, the Chiron publication (WO 02/079242) does teach epitope-containing fragments of their polypeptides in the first full paragraph on page 3 which epitope-containing fragments include those away from the amino acid position 371 of SEQ ID NO: 2-6. Additionally, as set forth under art rejections below, a biologically active fragment, for example, of SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4 and SEQ ID NO: 5 from invention I was known in the art at the time of the invention. Therefore, the lack of unity as set forth in the instant specification is proper, is maintained, and is hereby made FINAL.

Status of Claims

3) Claims 8 and 33-45 have been canceled via the preliminary amendment filed 03/29/06.

Claims 21 and 30 have been amended via the preliminary amendment filed 03/29/06.

Claims 1-7 and 9-32 are pending.

Claims 1, 2, 6, 7, 9, 10 and 14-32 have been withdrawn from consideration as not being directed to the elected inventions. See 37 C.F.R 1.142(b) and M.P.E.P § 821.03.

Claims 3-5 and 11-13 are under examination.

Information Disclosure Statements

4) Acknowledgement is made of Applicants' information disclosure statements filed 11/20/06 and 09/26/06. The information referred to therein has been considered and a signed copy is attached to this Office Action.

Sequence Listing

5) Acknowledgement is made of Applicants' raw sequence listing which has been entered on 04/07/06.

Priority

6) The instant application is a national stage 371 application of PCT/US04/33037, filed 10/01/04, which claims the priority benefit of 60/508,607, filed 10/02/2003.

Objection(s) to Specification

7) The specification is objected to for the following reason(s):

(a) Figure 3 includes two panels. Accordingly, the limitation 'Figure 3' in line 14 of page 7 of the specification should be replaced with the limitation --Figures 3A and 3B--. All references to the Figures throughout the specification should be changed accordingly.

(b) The use of the trademarks has been noted in this application. For example, see 'Triton-X' and 'Sepharose' on page 48; 'Coomassie brilliant blue' on page 49; 'Tween-20' on page 50; 'blotto' on pages 50 and 51; and 'Immulon 4' on pages 53 and 54. The trademark recitations should be capitalized wherever they appear. See M.P.E.P 608.01(V) and Appendix l. Although the use of trademarks is permissible in patent applications, the propriety nature of the trademarks should be respected and every effort made to prevent their use in any manner which

might adversely affect their validity as trademarks. It is suggested that Applicants examine the whole specification and make necessary changes wherever trademark recitations appear.

(c) The nucleotide sequence recited at lines 4-34 of page 56 of the specification contains more than ten nucleotide bases, yet is not identified by a specific SEQ ID number as required under 37 C.F.R 1.821 through 1.825. Any sequences recited in the instant specification, which are encompassed by the definitions for nucleotide and/or amino acid sequences as set forth in 37 C.F.R. 1.821(a)(1) and (a)(2) must comply with the requirements of 37 C.F.R 1.821 through 1.825. Note that branched sequences are specifically excluded from this definition.

APPLICANT MUST COMPLY WITH THE SEQUENCE RULES WITHIN THE SAME TIME PERIOD AS IS GIVEN FOR RESPONSE TO THIS ACTION, 37 C.F.R 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 C.F.R 1.821(g).

Rejection(s) under 35 U.S.C. § 112, Second Paragraph

8) The following is a quotation of the second paragraph of 35 U.S.C. § 112:

> The specification shall conclude one or more claims particularly pointing out and distinctly claiming the subject matter which the Applicant regards as his/her invention.

9) Claims 5 and 13 are rejected under 35 U.S.C § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which Applicants regard as the invention.

(a) Claim 5 is indefinite for including limitations within parentheses, for example: '(S1 coding sequence)'. This raises an indefiniteness issue as to whether or not the recited feature is optional. Furthermore, it is not clear what do S1, JL, RJL1 and L2 stand for.

(b) Claim 13, which depends from claim 5, is also rejected under 35 U.S.C. § 112, second paragraph, because of the vagueness in the base claim identified above.

Rejection(s) under 35 U.S.C. § 103

10) The following is a quotation of 35 U.S.C. § 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> **(a)** A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made

to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham v. John Deere Co.*, 148 USPQ 459, that are applied for establishing a background for determining obviousness under 35 U.S.C. § 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or unobviousness.

11) Claim 4 is rejected under 35 U.S.C § 103(a) as being unpatentable over Green *et al.* (US 6,100,380, filed 06/07/1995).

Green *et al.* disclosed a therapeutic or prophylactic immunomodulating (i.e., biologically active) Gly-Lys dipeptide contained in saline. See abstract and Example 7. The prior art Gly-Lys dipeptide inherently serves as a biologically active fragment of the instantly recited SEQ ID NO: 2, SEQ ID NO: 3, SEQ ID NO: 4 or SEQ ID NO: 5 wherein the fragment is present at amino acid positions 250 and 251 thereof.

Although Green *et al.* do not expressly teach an isolated nucleic acid encoding the immunomodulating Gly-Lys dipeptide, Green *et al.* explicitly taught that recombinant DNA technology may be used to express their dipeptide using transfection or transduction with a vector to transform a eukaryotic or prokaryotic host cell according to techniques described in Maniatis *et al. Molecular Cloning: A Laboratory Manual*, Cold Spring Harbor Laboratory, 1982. See lines 42-48 in column 7.

Given that the structure of the isolated biologically active peptide, Gly-Lys, was already disclosed by Green *et al.*, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to produce an isolated nucleic acid that encodes Green's biologically active Gly-Lys dipeptide using art-known recombinant techniques to produce the instant invention with a reasonable expectation of success. One of ordinary skill in the art would have been motivated to produce the instant invention for the expected benefit of using the isolated nucleic acid in the recombinant production of Green's dipeptide since Green *et al.*

expressly taught that their immunomodulating dipeptide can be produced using art-known recombinant DNA techniques.

Claim 4 is *prima facie* obvious over the prior art of record.

12) Claim 12 is rejected under 35 U.S.C § 103(a) as being unpatentable over Green *et al.* (US 6,100,380, filed 6/07/1995) as applied to claim 4 above.

The teachings of Green *et al.* as applied to claim 4 above are explained *supra* which do not expressly teach a composition comprising the nucleic acid in a pharmaceutically acceptable carrier.

However, adding an art-known pharmaceutically acceptable carrier to an art-known or art-suggested nucleic acid to form a composition was routine and conventional in the art at the time of the invention. Therefore, it would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to add an art-known pharmaceutical carrier to Green's nucleic acid as explained above with regard to claim 4 to produce the instant invention, since it was routine and conventional in the art to have a nucleic acid mixed with in a pharmaceutical carrier, for instance, before using it as a reagent.

Claim 12 is anticipated by Green *et al.*

Claim Objection(s)

13) Claims 3 and 4, and claims 11 and 12 that depend therefrom, are objected to for being dependent from a non-elected claim.

Remarks

14) Claims 4, 5, 12 and 13 stand rejected. Claims 3 and 11 stand objected to as explained above.

15) Papers related to this application may be submitted to Group 1600, AU 1645 by facsimile transmission. Papers should be transmitted via the PTO Central Fax number, (571) 273-8300, which receives transmissions 24 hours a day and 7 days a week.

16) Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAG or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.Mov. Should you have questions on access to the Private PAA system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (in USA or CANADA) or 571-272-1000.

17) Any inquiry concerning this communication or earlier communications from the Examiner should be directed to S. Devi, Ph.D., whose telephone number is (571) 272-0854. A message may be left on the Examiner's voice mail system. The Examiner can normally be reached on Monday to Friday from 7.15 a.m. to 4.15 p.m. except one day each bi-week, which would be disclosed on the Examiner's voice mail system.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Robert Mondesi, can be reached at (571) 272-0956.

/S. Devi/
Primary Examiner
AU 1645

January, 2009